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FORM PTO-1390 (Modified) (REV. 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE 480.1001 TRANSMITTAL LETTER TO THE UNITED STATES U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY 05 July 2002 (05.07.02) PCT/JP03/08482 03 July 2003 (03.07.03) TITLE OF INVENTION THERAPEUTICS FOR DIABETES MELLITUS APPLICANT(S) FOR DO/EO/US Akio INUI and Akihiro ASAKAWA Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. \bowtie This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 2. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), \boxtimes 3. (6), (9) and (24) indicated below. The US has been elected by the expiration of 19 months from the priority date (Article 31). 4 \boxtimes A copy of the International Application as filed (35 U.S.C. 371 (c) (2)) 5. is attached hereto (required only if not communicated by the International Bureau). a. 🛛 has been communicated by the International Bureau. b. 🗵 is not required, as the application was filed in the United States Receiving Office (RO/US). c. 🗆 An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). 6. \boxtimes is attached hereto. b. 🗆 has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. c. 🗆 have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 8. An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 9. \boxtimes An English language translation of the annexes to the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371 (c)(5)). A copy of the International Preliminary Examination Report (PCT/IPEA/409). 11. A copy of the International Search Report (PCT/ISA/210). 12 Items 13 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 13. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 14 15. \boxtimes A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. 16. 17. A substitute specification. 18. A change of power of attorney and/or address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. 19. A second copy of the published international application under 35 U.S.C. 154(d)(4). 20. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 21. \boxtimes Express Mail Label No. EV 382 791 765 US 22. 23. Other items or information: Application Data Sheet, Letter re. Priority, sequence listing (paper copy)

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U.S. A	PPLICATION NO. OF KNOWN, SEE 37 CFR PCT/DE03/00530					ATT	ATTORNEY'S DOCKET NUMBER 480.1001					
24.	The	following fees are submitted	d: Basic	: National Stage F	æ \$30	ο.α		CALCUI	LATIONS	PTO USE ONLY		
BASIC	Neither in	NAL FEE (37 CFR 1.492 (ternational preliminary exa nal search fee (37 CFR 1.44 lational Search Report not p	mination 45(a)(2))	fee (37 CFR 1.482) no paid to USPTO		• •	\$1080.00					
	Internatio USPTO b	nal preliminary examination ut International Search Rep	n fee (37 oort prepa	CFR 1.482) not paid to red by the EPO or JPO			\$920.00					
	☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO											
	International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)											
	☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)						\$100.00					
		•		ATE BASIC FE		OUI	= TV	9	300.00			
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Proces month	Processing fee of \$130.00 for furnishing the English translation later than								\$0.00			
				TOTAL NATI	ONAI	. Fl	EE =		\$300.00			
Fee fo	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).								\$0.00			
				TOTAL FEES	ENCL	os:	ED =		\$300.00			
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a.	⊠ A	check in the amount of	\$300	to cover the a	bove fee	s is e	nclosed.					
b.	□ P	lease charge my Deposit Ac	ccount No	o i	n the am	ount	of	to cover the above fees.				
c.		The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0552										
d.												
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR												
	1.137(a) or (b)) must be filed and granted to restore the application to pending status.											
SEND ALL CORRESPONDENCE TO:												
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 Seventh Avenue, 14th Floor New York, NY 10018 (212) 736-1940						SIGNATURE /						
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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Docket No.											
Applicant(s): INUI, et al		480.1001US									
pphodrit(o).											
Serial No.	Filing Date	Examiner	Group Art Unit								
To Be Assigned	Herewith	To Be Assigned	To Be Assigned								
Invention: THERAPEUTICS FOR DIABETES MELLITUS											
I hereby certify that the	e following correspondence:										
Thereby certify that the	s following correspondence.										
Application Filed Under 35 U.S.C. 371 with Accompanying Documents.											
<u> </u>	(Identify type	of correspondence)									
-	is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37										
CFR 1.10 in an envelo	ppe addressed to: Commissioner	for Patents, P.O. Box 1450, Alexa	andria, VA 22313-1450 on								
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VERIFICATION OF A TRANSLATION

I, the below named translator, hereby declare that:

My name and post office address are as stated below;

That I am knowledgeable in the English language and in the language in which the below identified application was filed, and that I believe the English translation of International Application No. PCT/JP03/08482 is a true and complete translation of the above-identified International Application as filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 27th day of December, 2004

Full name of the translator:

Hiroko EJIRI

Signature of the translator:

Post Office Address:

c/o YUASA AND HARA, Section 206,

New Ohtemachi Bldg., 2-1,

Ohtemachi 2-chome, Chiyoda-ku,

Tokyo, JAPAN